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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,674	10/17/2005	Kaw Yan Chua	15700.0002	1823

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
06/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,674	CHUA ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *138 and 173-179* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *138 and 173-179* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2009 has been entered.

2. Claims 138 and 173-179 are pending and currently under consideration as they read on a method for producing a polypeptide capable of stimulating an immune response against a molecule, the method comprising: (a) identifying a molecule against which the stimulation of the immune response is desired, the molecule consisting of a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2); and (b) forming a fusion protein by joining the molecule as a first portion thereof with a second portion being an Fve polypeptide having a sequence shown as SEQ ID NO: 6 and comprising a mutation selected from the group consisting of: a mutation from R to A at position 27 of that sequence (R27A) and a mutation from T to A at position 29 of that sequence (T29A).

3. The listing of references in the specification on pages 147-159 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP

§ 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 138 and 173-179 *are* rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: a method for producing the fusion proteins of SEQ ID NO:44 and 46 using nucleic acids, vectors and host cells, does not provide reasonable enablement for: **a method for producing a polypeptide** capable of stimulating an immune response against a molecule, the method comprising: (a) identifying a molecule against which the stimulation of the immune response is desired, the molecule consisting of a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2); and (b) **forming a fusion protein by joining the molecule as a first portion thereof with a second portion** being an Fve polypeptide **having a sequence shown as SEQ ID NO: 6** and comprising a mutation selected from the group consisting of: a mutation from R to A at position 27 of that sequence (R27A) and a mutation from T to A at position 29 of that sequence (T29A) of claim 138; in which the first portion comprises a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2) and the second portion comprises an FveR27A polypeptide **having a sequence shown as SEQ ID NO: 32** of claim 173; in which the polypeptide comprises a Der p 2-FveR27A fusion protein comprising **a**

sequence shown as SEQ ID NO: 44 of claim 174; in which the first portion comprises a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2) and the second portion comprises a FveT29A polypeptide **having a sequence shown as SEQ ID NO: 36** of claim 175; in which the polypeptide comprises a Der p 2-T29A fusion protein comprising **a sequence shown as SEQ ID NO: 46** of claim 176; in which the polypeptide further comprises a glutathione S transferase (GST) moiety of claim 177; **which comprises joining a first nucleic acid sequence encoding the molecule against which the stimulation of the immune response is desired to a second nucleic acid sequence encoding the Fve polypeptide to form a construct** of claim 178; and **in which the first nucleic acid and the second nucleic acid are joined in an expression vector, and the fusion protein is expressed from the expression vector** of claim 179.

Applicant's argument filed on 11/17/2009 has been fully considered, but is not found persuasive.

Applicant argues:

> "It is clear from the above that the specification describes the invention in sufficient detail to enable a person skilled in the art to make the invention. Applicants therefore submit that claim 138 and dependent claims are sufficiently enabled by the specification as filed. Applicants respectfully request reconsideration and the withdrawal of this rejection."

It is the Examiner's position that the specification discloses in the Appendix on page 165 the fusion proteins of SEQ ID NO:44 and 46 and in a method for their production in Example 13 on pages 117-121 and Figure 16.

The recitation of "having a sequence shown as" is open language that

encompasses polypeptides that may comprise subsequences of the recited sequences and may further comprise any number of additional amino acids added onto the N- and/or C-terminus of the disclosed peptide portion. Applicant is encouraged to amend the claims to recite, for example in claim 1, "comprises the FveR27A polypeptide of SEQ ID NO:6." The specification has not adequately disclosed the genus of methods recited and it would require one or ordinary skill in the art to perform undue experimentation to perform the invention commensurate in scope with the claims.

In addition, the claims are lacking steps that are required to produce the recited proteins. It is the Examiner's position that, as recited, claims 138 and 173-177 are directed to fusing or joining two proteins without the use of nucleic acids. Therefore, claims 178-179 which comprise nucleic acids are not enabled as being dependent upon claims 138 and 173-177 since the two proteins are not being joined in the method, rather the expression method results in a fusion protein. In addition, nucleic acid based methods require host cells to express the proteins. It is suggested that Applicants amend all the claims to recite the necessary elements for expression of the fusion proteins using nucleic acids, which is the only method disclosed in the specification for generating the fusion proteins.

In addition, Applicants are encouraged to amend the claims to recite "wherein" in place of "in which" in claims 173-179.

6. Claims 138 and 173-179 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of : a method for producing the fusion proteins of SEQ ID NO:44 and 4 using nucleic acids, vectors and host cells.

Applicant is not in possession of: a method for producing a polypeptide capable of stimulating an immune response against a molecule, the method comprising: (a) identifying a molecule against which the stimulation of the immune response is desired, the molecule consisting of a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2); and (b) forming a fusion protein by joining the molecule as a first portion thereof with a second portion being an Fve polypeptide **having a sequence shown as SEQ ID NO: 6** and comprising a mutation selected from the group consisting of: a mutation from R to A at position 27 of that sequence (R27A) and a mutation from T to A at position 29 of that sequence (T29A) of claim 138; in which the first portion comprises a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2) and the second portion comprises an FveR27A polypeptide **having a sequence shown as SEQ ID NO: 32** of claim 173; in which the polypeptide comprises a Der p 2-FveR27A fusion protein comprising **a sequence shown as SEQ ID NO: 44** of claim 174; in which the first portion comprises a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2) and the second portion comprises a FveT29A polypeptide **having a sequence shown as SEQ ID NO: 36** of claim 175; in which the polypeptide comprises a Der p 2-T29A

fusion protein comprising **a sequence shown as SEQ ID NO: 46** of claim 17 and as applied to claims 177-179.

Applicant's argument filed on 11/17/2009 has been fully considered, but is not found persuasive.

Applicant argues:

> "Accordingly, the specification sufficiently describes the claimed invention in full, clear, concise and exact terms and satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Thus Applicants respectfully request reconsideration and withdrawal of this rejection with respect to claim 138 and dependent claims thereof."

It is the Examiner's position that Applicant has disclosed only a method for producing the fusion proteins of SEQ ID NO:44 and 46 using nucleic acids, vectors and host cells; therefore, the skilled artisan cannot envision all the contemplated method possibilities recited in the instant claims.

The recitation of "having a sequence shown as" is open language that encompasses polypeptides that may comprise subsequences of the recited sequences and may further comprise any number of additional amino acids added onto the N- and/or C-terminus of the disclosed peptide portion. Applicant is encouraged to amend the claims to recite, for example in claim 1, "comprises the FveR27A polypeptide of SEQ ID NO:6." The specification has not adequately described the genus of methods recited.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-

9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 18, 2010

/Nora M Rooney/

Examiner, Art Unit 1644